BSE Limited 1st Floor, P. J. Towers Dalal Street Mumbai–400 001 Code: 532321	**National Stock Exchange of India Limited** Exchange Plaza, 5th Floor, Plot No. C/1, G Block, Bandra-Kurla Complex, Bandra (East) Mumbai–400 051 Symbol: CADILAHC
Date: August 20, 2021	
Sub.: Transcript of Company's Q1 FY22 post results conference call	

Dear Sir / Madam,

Please find attached the transcript of the Company's Q1 FY22 post results conference call held at 4.00 p.m. on August 11, 2021.

Please find the same in order.

Thanking you,

Yours faithfully,
For, **CADILA HEALTHCARE LIMITED**

DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2021.08.20 10:15:47 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

“Cadila Healthcare Limited Q1 FY22 Post Results Conference Call”

August 11, 2021

MANAGEMENT: **DR. SHARVIL PATEL – MANAGING DIRECTOR, CADILA HEALTHCARE LIMITED**
MR. GANESH NAYAK – CHIEF OPERATING OFFICER & EXECUTIVE DIRECTOR, CADILA HEALTHCARE LIMITED
MR. NITIN PAREKH – CHIEF FINANCIAL OFFICER, CADILA HEALTHCARE LIMITED
MR. VISHAL GOR – SENIOR VICE PRESIDENT, CORPORATE FINANCE, CADILA HEALTHCARE LIMITED
MR. ALOK GARG – SENIOR VICE PRESIDENT, CADILA HEALTHCARE LIMITED

Moderator: Ladies and gentlemen, good day and welcome to Q1 FY22 Post Results Conference Call for Cadila Healthcare Limited. As a reminder, all participants' lines will be in listen only mode, and there will be an opportunity for you to ask questions after the presentation concludes.

Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. Participants on webcasts are requested to mute your audio to avoid any echo while asking a question.

I now hand the conference over to Mr. Ganesh Nayak – COO and Executive Director of Cadila Healthcare Limited. Thank you and over to you, sir.

Ganesh Nayak: Good evening, ladies and gentlemen. Welcome to our Post-Results Teleconference for the Quarter Ended June 2021. I do wish that you and your families are keeping safe and well. On today's call We have with us Dr. Sharvil Patel - Managing Director; Mr. Nitin Parekh - Chief Financial Officer; Mr. Vishal Gor - Senior Vice President Corporate Finance, and Mr. Alok Garg - Senior Vice President from the Managing Director's office.

This quarter onwards, we have started the practice of sharing quarterly results investor presentation, which we have posted on our website and filed with the stock exchanges. I am sure you would have received the same.

Among our two key markets, India and the US, the contribution from the India geography has increased. This has offset some of the challenges in the US during the quarter, resulting in a healthy double-digit growth in revenues, and in EBITDA with an improvement in operating margins. Coming to the quarter, despite the onset of the second wave of COVID-19 in India, and the consequent challenges posed by it, our business grew in double digits, aided by strong performance in the India geography.

With that, let me take you through the financial numbers for the quarter gone by. As you are aware, the transaction of sale of our Animal Healthcare Established Markets undertaking of Zydus Animal Health and Investments Limited (AHESTM) was completed recently on the 14th of July 2021. The consolidated financials for the period ended June 2021 up to the PBT level, do not include the financials of AHESTM and financials of the previous quarter and previous financial year have also been restated to correspond with the figures of the current reporting period. Net profits from AHESTM for all the periods have been shown separately as "profits from discontinued operations" in the profit and loss account.

During the quarter, we posted consolidated revenues of Rs. 40.3 billion up 15% year-on-year. Consolidated EBITDA improved during the quarter and stood at Rs. 9.33 billion up 18% year-on-year. EBITDA margins for the quarter stood at 23.2%, which is an improvement of 140 basis points on a quarter-on-quarter basis.

Various process simplification and efficiency enhancement initiatives aimed at optimizing the costs resulted into the improvement in EBITDA margins, despite the inflationary pressures. Consolidated PAT for the quarter was Rs. 5.87 billion up 29% year-on-year.

Our India geography comprising of Human Health and Consumer Wellness Business, which contributed to 50% of the consolidated revenues during the quarter witnessed a very strong growth of 43% on a year-on-year basis and registered sales of Rs. 19.4 billion. The US geography comprising of generics and specialty portfolio posted sales of Rs. 14.5 billion during the quarter, down 4% quarter-on-quarter. Our emerging markets business grew by 17% on a year-on-year basis and posted sales of Rs. 2.77 billion. On a sequential basis, the business grew by 11% during the quarter.

Now, let me take you through the operating highlights for the first quarter of FY22 for each of our business lines. Starting with our Human Health Business in the India geography, the pharmaceutical market in India registered a healthy growth of 37.2% during the quarter gone by, aided by the lower base of the previous year and contribution from the COVID portfolio. In line with the market our business also registered a strong growth during the quarter.

Overall, our Human Health Formulations Business posted sales of Rs. 13.57 billion during the Q1 FY22, up 64% on a year-on-year basis. The growth was supported by both COVID portfolio as well as good performance of the base business. Branded Generics business grew by 67% on a year-on-year basis during the quarter. We gained market share in the anti-diabetic, anti-infective and the nutraceuticals therapeutic areas during the quarter viz-a-viz the corresponding quarter of the previous year.

Going forward with a reduction in the COVID-19 cases across the country and relaxations of restrictions, we expect the demand for medicines to normalize due to increased footballs in the doctor clinics.

During the quarter, our consumer business witnessed a strong growth in five out of seven brands that resulted in an overall 10% growth on a year-on-year basis, and revenues of Rs. 5.9 billion. The summer season brands Nycil and Glucon-D could not capitalize on their full potential due to a short summer and lockdown in many states. With markets opening up, we see strong surge in demand across channels.

Now, let me take you through the performance of our US formulations business. As mentioned earlier, the business saw a sequential decline in revenues during the quarter gone by. Reduction in cases of supply disruption in the market resulting in limited one-time opportunities and pricing pressure in some of our products led to this decline. However, despite the increased competition and pricing pressure, our US generics business could grow the overall volumes during the quarter. Recently, in the month of July, we received the final approval for Fulvestrant Injection, which is the first approval of a complex product from the biologics manufacturing facility. This

product got the approval in the first review cycle by the USFDA and was approved in less than 10 months of filing.

Recognizing the importance of digitalization and advanced analytics in improving healthcare delivery, offering better customer experience and building responsive back end, we have taken multiple digitalization initiatives in our human health formulations and consumer wellness business in India and also in our manufacturing operations. In the human health formulations business in India, we are working on a platform technology that will connect the entire value chain to drive quality, productivity and operational efficiency, resulting in enhanced patient centricity, better prescriber engagement, comprehensive disease management and an improved healthcare delivery experience to all the stakeholders.

On the consumer wellness front, the digitalization initiative will help get real time demand visibility across channels, market trend analysis through predictive modeling, efficient management of inventory, better ROI on trade spends and also enable close monitoring and governance of other functional KPIs.

On the manufacturing operations side, we are working on the use of advanced digital and analytical tools that will enhance overall compliance and efficiency through simplification, resulting in increased throughput by unlocking equipment effectiveness, productivity by avoiding redundancies and adopting lean work practices to optimize costs.

During the pandemic, we saw opportunity to completely relook at our entire operational spend and initiated the process of zero-based budgeting in our major business, i.e. Human Health Formulations business in India. This initiative will help optimize both direct and indirect spend and build internal capability to attain sustained savings over time.

The manufacturing operations and zero-based budgeting initiatives put together are expected to improve our operating margins by 80 to 100 basis points. Now, this concludes the business review. I would now request Dr. Sharvil Patel to take you through the progress and initiatives in our innovation program. Over to you, Dr. Sharvil Patel.

Sharvil Patel: Thank you, Mr. Nayak, and good evening, ladies and gentlemen. As you all know, continuing with our efforts to combat the COVID-19 we have applied for an EUA to the Office of DCGI. for ZyCoV-D vaccine, with an interim phase three clinical trial efficacy data for the two-milligram dose study. The trials were conducted in over 28,000 volunteers at more than 50 clinical sites spread across the country and during the peak of the second wave of COVID-19 reaffirming the vaccines efficacy against the new mutant strains, especially the Delta variant.

This was also the first time that any COVID vaccine has been tested in the adolescent populations in the age group of 12 to 18 in India. Around 1,000 subjects were enrolled in this age group and the vaccine was found to be safe and very well tolerated.

We have also submitted the dossier of ZyCoV-D vaccine for an EUA to DCGI with a trial data for the three-milligram dose study also which is a two visit vaccine. On the NCE front, recently, in the month of July, we are very happy to say that the EMA, the European Medicines Agency granted orphan drug designation to Saroglitazar Magnesium for Primary Biliary Cholangitis indication. ODD status provides with an exclusivity for 10 years if the treatment gets approved. PBC is a disease with a global prevalence of approximately 40 cases per 100,000. Women are much more likely to be affected by PBC than men, and the incidence increases after the age of 50. Across the world PBC primarily affects an estimated 1 in 1,000 women over the age group of 40. Global market for PBC treatment is expected to grow at a CAGR of 36%+ from 2018 to 2026 and is expected to reach approximately $11 billion by 2026.

Approximately 40% of the patients are either non or partial responders to the current modes of treatment, resulting in a highly underserved patient population. We are hoping that Saroglitazar will solve for one of these critical outcomes and become a successful product as we move forward.

In India, we received an approval from CDCO to initiate phase one clinical trial for a novel multi dose anti-malarial molecule ZY19489. This molecule has already been trialed in Australia.

Coming to the biosimilars. During the quarter, we launched Trastuzumab Emtansine the first ADC biosimilar and a highly effective drug for the treatment of both early and advanced HER2 positive breast cancer under the brand name Ujvira. The drug has significantly reduced the cost of treatment by almost 80% for all patients.

Talking on 505(b)(2) and specialty initiatives, during the quarter, we received a response from the USFDA against a pre-NDA meeting for a pain management product. NDA for this product is expected to be filed during the current financial year.

During the quarter we completed six in-licensing deals. Five out of the six products are expected to start contributing to the revenues from FY23. Cumulative number of such in-licensed products now stands at 24. Out of all the in-licensed products for two products we are likely to hold an exclusive first to file status and are likely to have 180-days exclusivity upon launch. Thank you, and we will now move over to the Q&A session. Over to the coordinator.

Moderator: Thank you very much. Ladies and gentlemen, we will now begin the question-and-answer session. The first question is from the line of Tushar Manudhane from Motilal Oswal. Please go ahead.

Tushar Manudhane: Sir, just on these in-licensing deals, you alluded for revenue contribution from FY23 onwards. Any further color on this in terms of further contribution of how much this revenue contribution can be?

Sharvil Patel: So, I think most of the in-licensing deals we have done are where we have gaps in our portfolio or where we may have lost some opportunity on first to file. So, the in-licensing opportunities are generally products which are very niche or products which have low competition.

So, they all have a significantly good commercial potentials than any of the normal molecules. So, they are obviously the high value products. Exact value is not possible to give in terms of the next two to three years forecast for that. But some of them do fall in the complex injectable space and some in the oral space. As I said in my call also that two of these products is also where we have got 180-day exclusivity potentially. So, they are all meaningfully large value products.

Tushar Manudhane: And these will be manufactured at….

Sharvil Patel: Largely many of them are manufactured by the Company whom we license from because they are complex in nature, either the API or the formulation. Few of them we will do manufacturing ourselves, but by and large, many of them are sold through the licensing.

Tushar Manudhane: And lastly, how much would be the share of COVID related revenue for the quarter in the human health business?

Sharvil Patel: I could not understand the question?

Tushar Manudhane: Sir, the share of COVID related revenue in the human health business for the quarter gone by?

Sharvil Patel: So, large part of the revenue majority of the revenue was obviously COVID related was Remdesivir. Minus Remdesivir, our growth was 35% plus for the branded formulations.

Moderator: Thank you. Our next question is from the line of Kunal Dhamesha from MK Global. Please go ahead.

Kunal Dhamesha: So, first on the US business. We said the weakness is attributed one of the factor is one time buy. So, was that I think that should be positive impact, right? So, was that in this quarter, or the last quarter we had some one time buy which did not recur in the first quarter?

Sharvil Patel: So, one time buy we have been seeing it in the last couple of years because of disruption in supply chain. In the last six months we have seen this one-time buys have dried up because there is very little issue with supply chain in the US. So, we have not seen any meaningful one time buys in the last six months.

Kunal Dhamesha: Sure. And secondly, I think we have launched like four products in US vis-à-vis our target was somewhere around launching 30 to 35 products. So, are we still on track to achieve that?

Sharvil Patel: So, in the US, we still do expect to get close to 50 plus approvals, some being tentative, and we will achieve up to 30 plus of launches.

Kunal Dhamesha: Sure. And secondly, on the vaccine opportunity. Now that around 55% of the adult population has been vaccinated with at least one dose and every lost month is kind of reduces the remaining market by at least 20%, 25%. So, how do you see this opportunity now and in the adult market, as well as in the adolescent, and on the adolescent front, have we also submitted for emergency use authorization for our vaccine?

Sharvil Patel: So, on the second question, yes, we have submitted for EUA for the adolescent population. And we are also hoping we will see approval for that. And as soon as we know anything more, we will apprise everyone about it. With respect to the opportunity for COVID, our current capacities that we have if we fully manufacture ourselves is at the max between 10 million to 15 million doses monthly, which is not very large, in terms of the overall need of the vaccination.

So, even at the adult population, I think, for us, I do not think the difficulty will be in being able to secure the business for the quarter, the manufacturing capacities that we have. So, we still feel we should be able to supply whatever we can make because we are not, you are talking about 1 crores doses or 1.5 crores doses, which are not very large in the overall requirement point of view.

Kunal Dhamesha: And if I may say squeeze in the last one. In terms of vaccine manufacturing, have we started stockpiling because I believe our plant was supposed to be commercialized somewhere in July? So, have we started stockpiling in the anticipation of approval, or we will start manufacturing at commercial scale after approval?

Sharvil Patel: So, in our smaller facility, we have started manufacturing commercially for stockpiling. In our new facility the activities are starting as of this week.

Moderator: Thank you. Next question is from the line of Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: So, I was just asking about the US business. Any specific reasons that we have seen a kind of sequential correction in the US business, because we know that the previous quarter was not a great quarter in any manner about the flu sales contribution? So, hence there was no reason for a kind of sequential correction, although there was a kind of issue of a pricing pressure? And given that, what is the kind of outlook that you are having for the full year in US?

Sharvil Patel: So, in the US, two things, which we spoke about in our conference call. One is there is a lot more competition that we get to see on established products and new products with for approvals that have come through both from existing and new players. So, that is something that has definitely happened to the market where you are seeing far more competition.

Second is that there have been least supply disruptions during the last one year. And that also means that what we used to get to see opportunities of one-time sales by being able to supply products, which are in shortage, that issue has come down for the oral drug. So, that is the second part by which we see some gaps. And thirdly, we have said that because of the lower activities at the prescription level, some of the products the prescription volume has come down, which correspondingly means that the buying also reduces.

So, those are some of the things that have happened, which has led to this. For us for annual point of view, we are still looking at low single digit growth for this year. And if some of the critical new products succeed, we can see some better traction on that. So, that is our current estimate. In terms of the next two to three years we believe that both transdermal and our specialty injectables, and some of the complex oral solid products will allow us to then scale up from the current levels of what we are at.

Surya Patra: Second question is on the COVID portfolio and the anticipation from the vaccine or any such issue. So, you have obviously indicated about it already. But I am saying let us say given the recent developments about the approval for the combination of Covishield plus Covaxin the approval of J&J's single dose and your recent just the commentary to the earlier question that your expectation of 1 crores to 1.5 crores kind of per month target that is anyway can be achievable anyway. So, that means, are you kind of moderating your expectations over here?

So, my second question was on the vaccine opportunities. So, I was saying that given the recent developments about allowing or approval of the Covishield plus Covaxin kind of mix in India and the single dose of J&J and sir, right now you have mentioned about your expectation of 1 crores to 1.5 crores per month kind of volume. So, whether that is a kind of moderation from your earlier expectation that you were thinking about achieving 3 crores to 5 crores kind of level by December or so? So, anything on that front?

Sharvil Patel: So, I think your question I understand, but I think you are mixing two things. When I say 1 crores to 1.5 crores that is monthly and what we said 3.5 crores was till December. So, we have not moderated our stands yet. We believe that currently, whatever we will be able to make, we can find an opportunity of market for it in India and obviously there is market outside. But currently let us focus only on India.

So, we do not see any concern on that. If you look at the manufacturers today in India Covishield has a very large manufacturing capacity, but other than that, there is nobody who is achieving more than 1 crores to 2 crores and any of the approved vaccines have not reached commercially availability at all in India. So, I think in India, we still require a lot of vaccines. And for us, we believe that with whatever understanding we are, we have currently a very strong demand for our vaccine both for the use in the current form, but also for the adolescent use, where there is currently none approved.

So, as I said till end of the year, we believe anywhere around 3 crores plus we hope to manufacture and supply and that is a full capacity. So, we are only making to full capacity.

Surya Patra: Okay. Sir, my next question is about even the expectations about let us say Virafin what we have been so excited about. So, obviously the number of COVID cases has come down. So, is it better to think that okay, the opportunity is really drying out here, and that is one and a clarification about this minority interest higher since last couple of quarter or last two quarters, is it because of that there is a kind of COVID related benefit that is seen in the consumer business and hence, the minority interest is looking a bit elevated?

Sharvil Patel: So, on the first question, I mean, if we all understand what is happening to with COVID-19, and the impact it has everywhere, and the way it is moving, you know that the infections and the peaks come in waves and in cycles. So, we have obviously gone through a very strong second cycle or second wave of COVID. But we know that with what we are seeing in Europe, in the rest of the world, we know that there is an imminent way of the third wave that will be there.

So, the opportunistic products or products that are related to COVID will obviously make more sense when you see those kind of problems around. For Virasin specifically, we are also looking to export it in other countries. And we are also looking to build outside India business beyond what is India but currently what you say is right in India, there are much lower cases and prevalence. So, currently the need for COVID drugs is lower.

But both for Virafin, Remdesivir we will see a potentially a good export market that we want to build for. For Remdesivir we have significantly good export business and India businesses, and we will do the same for Virafin also. Related to your second question, maybe Vishal or Nitin Bhai can take it up.

Vishal Gor: Yes, so Surya, actually, the non-controlling interest is mainly for Zydus Wellness. And as you know Zydus Wellness is a seasonal business. So, it is not evenly spread across all the four quarters. So, Quarter 4 of the financial year and Quarter 1 of the financial year are the main seasons where you will see higher top line as well as profit in that business. And quarter 2 and quarter 3 are relatively lean, because the season for two or three of their brands is not there. So, as a result, you will see this kind of trend every year.

So, quarter one of any year in quarter four of any year we will have higher profits in Zydus Wellness resulting into higher non-controlling interest also. One exception was the last financial year where because of first wave of COVID Zydus Wellness did not have good profits. And as a result, the non-controlling interest was lower. This quarter onwards it has normalized.

Moderator: Thank you. Next question is from the line of Anubhav Aggarwal from Credit Suisse. Please go ahead.

Anubhav Aggarwal: My first question is on the back of the ZyCoV-D vaccine. Just trying to understand that phase 3 efficacy data difference between the three dose and the two dose? I think you have declared three dose, but you have not I think mentioned about two dose Can you just talk about Sharvil Bhai, that how are the two different from efficacy front?

Sharvil Patel: So, the difference between the three dose, I mean, the three visit and two dose, the amount of dose given is the same. It is just that instead of giving between 0, 28 and 56 days, we do only two times dosing between 0 and 28 days. So, we believe that will bring obviously far more patient compliance and ease of administration.

So, I think from the amount of vaccine given it is the same between the two arms and what we have, once we obviously get through the registration of that we will explain more, but we have seen equal and better immunogenicity and antibody response in the two visit versus a three visit and that is where we believe that that could be the potential mode of use for this vaccine as we move forward.

Anubhav Aggarwal: So, effectively you are saying the efficacy data is used in better in the 3mg versus 2mg one. So, what about the safety data has that been comparable as well?

Sharvil Patel: Yes, so the safety wise also there have been no safety events or any serious safety events with this arm also. And across all the from phase one till now we have not had any safety concerns and that obviously has been published and shown to the regulator. So, on that we are fine, and I just said it has better immunogenicity.

So, it could potentially have a higher efficacy but currently I would say conservatively to assume similar efficacy would be right.

Anubhav Aggarwal: And what kind of population base like you ran the trial on 28,000 patient on 2mg one. On 3mg one what was the population based on which you run the trial?

Sharvil Patel: So, the 3mg trial has been done on the immunogenicity point of view, so it has been done in close to I do not have the exact number right now but around close to I think 800 to 1,000.

Anubhav Aggarwal: Okay and for the adolescent are you going for the 2-dose version even for the adolescent or for them it is a 2mg one only?

Sharvil Patel: So, again these are all for the regulators to discuss. We believe with the body of evidence and data we have shown it potentially will also be a 2-dose regimen, two visit regimen.

Anubhav Aggarwal: Sure. And for the export markets have you already started applying or once you get an emergency use of authorization here in India then you will start applying to the export market?

Sharvil Patel: So, it is still work in progress. For us the current capacities that we have, we feel we will not have enough capacity to serve India. So, to look at export is not something practical right now. Because obviously we would not be able to make any supplies, but we are looking at partnerships and to see whether we can partner for future supplies and maybe give technology transfer to other countries for manufacturing of these vaccines. Few of them have approached us. So, we are in those discussion phases, but in the near term we are largely only focused for India right now.

Moderator: Thank you. Our next question is from the line of Forum Parekh from Choice Institutional Equities. Please go ahead.

Forum Parekh: Yes, so my question is on wellness, it is a follow up question. Sir, you just said that Q1 and Q4 is like the seasonally strong quarter. So, would it be right to assume that in the next two quarters the growth rate will taper down to what it is reported in Q1?

Sharvil Patel: So, growth is obviously corresponding to the last quarter of the previous financial year. So, it is not an impact of growth, it is the absolute sales. Quarter four and quarter one is larger versus quarter two and quarter three. But we are not talking about growth tapering down we are talking about the size and size of the business being different between the quarters.

Forum Parekh: Okay, and sir, if you can just throw some color on the US business like we are seeing Delta variant over there and price erosion. So, what would be the probable impact be on the US sales all of these situations?

Sharvil Patel: So, currently, the impact mostly is because of the price or more competition and less disruption in supply. So, I think the growth possibilities only when you are with the possibilities of new launches that we get to do, and US is a cyclical business. So, it goes through this cycles of consolidation and again, then disruption.

So, we believe that if you have the breadth of portfolio, which is large enough, and if you have good operational efficiencies and good inventory positions, one will see an opportunity that one will get to build on from the existing portfolio. And the rest is obviously to file a new portfolio, which we have been doing and launching new products, and slowly building two franchises, the transdermal side, and the injectable side, which can be very large and sizable for the organization.

Forum Parekh: Okay, and if I may just ask one more question. I just wanted to know, how much percentage of COVID drugs do we export?

Sharvil Patel: Currently, it is only Remdesivir in a way, because the government had blocked exports for a very long time. So, currently is only Remdesivir and no other drugs, which are more COVID. related.

Forum Parekh: Okay, so that would be like less than 5% of the COVID portfolio that we would be exporting?

Sharvil Patel: The export of Remdesivir, I do not have the exact number, but it is not very large for the last quarter.

Moderator: Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: First one is on the US growth trajectory. So, much has been talked about, kind of approvals, expected launches, JVs, and for injectables and all but qualitatively, I mean, on this base that we are clocking around $200 million, do we see growth going forward in this year and next year? Or do we see that these opportunities that we spoke about this would be able to cover the base business price erosion? How do we see this for the next 6 to 12 months, or over the next 12 to 18 months?

Sharvil Patel: So, for the immediate quarters, we are seeing we will do a little bit better. So, there will be some minor growth or a single digit growth that we are aspiring for in the next quarter and beyond. Going forward in the next financial year, with some new products, some settlements that we have, and more of some of the injectable launches that we hope to see very soon.

And some of the more complex oral new product approvals that we are getting to see in the next quarter, we hope we can build upon that base to minimize the erosion that we may see on one of our Mesalamine franchise. So, that should offset that.

And then more new product launches can build upon the traction on the US business. So, I still believe for the next three to four quarters, we will see a low single digit growth and maybe protecting the base would be the right way to look at it. Other than some opportunistic things that we get to see which we do not, we cannot, we do not know off and which can plan for. But going forward I think the other portfolios coming in, which is injectables, and transdermal with the clearance, once we get from Moraiya, we will get to see some better traction on new product successes.

Prakash Agarwal: Yes, I mean, that pulls me to the second question on Moraiya. So, there is any update on desktop inspection? And we hearing that couple of inspections have started in Hyderabad. So, any update there? Or what are you hearing? Or what are you getting prepared for?

Sharvil Patel: So, one, we have now at least got the clearance from the FDA point of view understanding that we have finished our process of corrective actions and they have been submitted and they have been accepted by the FDA and the FDA will schedule for an audit.

Now the audit in terms of physical audit or any other form of audit is still unknown, but we are expecting an audit is what we can say.

Prakash Agarwal: So, what I understand the CAPA plan, you already executed the CAPA plan as required?

Sharvil Patel: Yes, it has already been executed and discussed and closed. We are now we need a physic some sort of inspection to get triggered for getting out of the warning letter.

Prakash Agarwal: Perfect. And lastly, on the margin side, there was a mention on this, you know, we are expecting efficiencies to kick in and margins to improve by 80 bps to 100 bps that is on the current base of 20% to 23% or that was more like a generate statement? How do we think about margin expansion for this year and next year?

Sharvil Patel: So, it is on a current base.

Prakash Agarwal: So, it is about 22% to 23%?

Sharvil Patel: Yes.

Prakash Agarwal: And this is over 12 to 18 months?

Sharvil Patel: Yes in 12 months.

Moderator: Thank you. Our next question is from the line of Kunal Dhamesha from Emkay Global. Please go ahead.

Kunal Dhamesha: So, on the generic injectable business, specifically in US, what is our aspiration and what is our current size in terms of number of products, and maybe if you can share value, and from which plant our future pipeline is kind of priced?

Sharvil Patel: So, our aspiration for the US injectable business is that we want to build at least $250 plus million business in the next three to four years. And that is our current estimate. And this includes a lot of important complex products as well as large number of products that we hope to still continues to file. Our critical sites for US injectables business are our site in Vadodara, which is Liva, which has four lines, and it is approved by the USFDA at least two of the lines are already approved.

We have one new site which is a biologic site where we got prefilled syringe approval and so that site stands approved and then we have our Alidac site which manufactures cytotoxic injectables where we sell Liposome Doxorubicin from and hope to file for other injectables also there. And then we have one of our joint venture sites, which does CMO work for us also where we will also see some oncology filing and launches. So, these are largely the plants which are used.

They all have currently a very good track record of multiple inspections and have done well with their inspection. So, they are all good. In terms of complex injectables one strategy that we do

also have is that we also have partnered in product where these products are partnered in from European and some of the Asian countries. And they also have a good track record on the FDA, and we will be also launching many of the injectables through in-license portfolio.

Kunal Dhamesha: Sure, and if you can provide the size of the current US injectable portfolios?

Sharvil Patel: It is about $35 million, I think?

Vishal Gor: Yes, it is about $35 million per annum.

Kunal Dhamesha: And second question again coming back to vaccine. So, I believe we had one data request from the DCGI, and I think we have complied to that. So, at this moment, what is pending is there another data requests from them or we are just waiting for their response?

Sharvil Patel: So, we have one data point that we had to provide last week, but it is being done at a government instituted lab but that has got delayed. So, that is getting submitted tomorrow or day after. After that, for at least we believe currently for the approval phase, we would have completed most of our data sequence.

Kunal Dhamesha: And one last on the vaccine facility, that we have kind of created. So, what other maybe dosage form or other kinds of vaccines or other formulations we can produce in that facility?

Sharvil Patel: So, there are vaccines has two plants. One is a drug substance plant, and one is a drug product plant. The drug product plants are existing facilities which make other vaccines and other products also so that is fungible. With respect to the drug substance plant for the DNA vaccine, it is a recombinant vaccine plant.

So, it can take up some other recombinant products. But currently for the foreseeable near future obviously we do not have any other capacities to do anything with this plant. So, this will be currently dedicated only for the DNA vaccine. Potentially, we are also looking at developing more products, more vaccine platform using this technology.

So, that will be the ongoing work that will continue for this. So, it is a recombinant plant. So, in a way it is after some modification, it can be repurposed for some recombinant biologic, but currently, this capacity is going to be fully dedicated for only vaccine products.

Moderator: Thank you. Next question is from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.

Nimish Mehta: A lot of my questions have been answered. Just one thing on the US side like are we likely to launch other mesalamine franchise especially products like Delzicol in the near future? Some outlook on there will be helpful?

Sharvil Patel: Could you repeat the product name, I could not hear it well?

Nimish Mehta: Delzicol or any other Mesalamine product?

Sharvil Patel: Yes, so we do have a portfolio of at least three more Mesalamines that we want to launch, and we would be launching some of them very soon.

Nimish Mehta: Meaning in this year itself, this financial year itself?

Sharvil Patel: Yes.

Nimish Mehta: And second, just a quick update on the domestic business. How many products are we likely to launch this year in the domestic market and how many of them would be first to market?

Sharvil Patel: So, currently, we have a portfolio of about 35 molecules that we are working which we want to launch which will either have limited competition or be first to market. In the recent times we have launched a good amount of franchise in the diabetes space including Vildagliptin, Teneligliptin and in future we will be launching some of the other Gliptin. So, that is one. Then we have launched Dydrogesterone, which is again one of the very few limited competition product.

So. large part of our future portfolio is driven towards launching low competition or sort of first generic when we launched our biosimilar against the only generic in India and in the world.

So, we will see a healthy pipeline of products that would be first in India, either first generic or potentially first likely**.** We also have Desidustat that we hope to file by end of this year.

So, we would see a large part of portfolio being complex and first kind of launches in India. Beyond that obviously Lifecycle Management and product lifecycle extension happens through doing formulation research that we also continue to do for our products.

And COVID is a different year we have launched quite a few COVID products but on average, we are looking to launch anywhere between 30 to 45 new launches in India.

Nimish Mehta: And a lot of them will be first time in the market, right?

Sharvil Patel: So, 30 to 45 in a year will not all be first time, but if you take a three-to-four-year view then at least 30 to 35 like important critical launches which have limited competition or are day one launches.

Moderator: Thank you. Our next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: Sharvil Bhai, this is about the ZyCoV-D vaccine. So, question number one, what are your thoughts on the efficacy study for adolescents?

Sharvil Patel: So, efficacy is never done in cohorts like that. When you do a large phase three you do with general efficacy, and then you do immunogenicity, which is divided in different cohorts, older age group, comorbidities and then the younger age group. So, we do not do separate efficacy right now, that will get created once we have a larger set of data.

So, we can talk about overall efficacy, which is a good representation of the overall efficacy. What we do is immunogenicity for all these cohorts to make sure that the antibody response and the IGG as well as the neutralizing antibody response, as well as the T cell response, or the interferon gamma challenge are all similar, or they are giving different trends and we have seen much good, very good trend for obviously older age group. In children, we have seen a higher trend on higher antibody formation.

So, potentially it could mean that they have a far better higher protection. So, that is how the all the studies are planned.

Sameer Baisiwala: So, when you get the approval, you get it for both adolescents and adults?

Sharvil Patel: That is what we will be hoping for. But I mean, once we get the regulator's node, we can talk more about it, but we do have filed for all of this data.

Sameer Baisiwala: Okay, any timelines when you expect approval and then get into the market?

Sharvil Patel: So, again, it is very difficult to predict that, I will say the last set of information we believe we will submit in the next one to two days. And by and large, it is a rolling review that happens. So, all the other information has already been reviewed. So, if everything is okay, and if they do not see and we also do not see an issue in the last data and the data is fine, we can potentially see an approval in the next one to two weeks maximum.

Sameer Baisiwala: Okay, so this is pretty close. And so, what is the market access work being done? If you can just share with us, would you be routing it through all private channels, some tie ups that you have done? Would it be for, because their volumes are not that large, would you be going all India or just the western market?

Sharvil Patel: So, currently there are three opportunities. One is the government sourcing, which potentially could be the largest sourcing that happens right the government did commit that they may be potentially buying for many of the vaccines 75% and leaving 25% for the retail.

The second is we have also done a lot of activity and created a lot of capability on the digital side to build for the whole supply chain and dose administration and the other things that are required in terms of patient support and other required things. So, that whole activity is in place

linking it with the app to make sure that the right dosing, and everything happens, and we are gone beyond it in terms of providing far more critical information.

So, all of that is done. We do have requests from institutions and large institutions and midsized institutions for direct buying, which we have in principle agreed to do so. So, as soon as we get an approval as soon as our pricing gets cleared, and as soon as the government commits to their quantities, accordingly we will obviously then supply to the rest of the market as well. Currently, it is a question, current demand obviously we have what we produce we can we have expectations from customers for more than that. So, we will see how we will be able to commit to the different supplies.

Sameer Baisiwala: Okay, one final one on this. Sharvil Bhai, if you I do not know how comfortable you are talking. Can you talk a bit about the pricing for this government versus private and your margin expectation on this?

Sharvil Patel: So, we have not had that yet. So, currently we have a reference price of approval for the government purchases. So, obviously, every vaccine is different, and the technology is different as well as the investments are different. So, that is the place where we still need to discuss with the authorities, but obviously it will be I mean, we already know the floor price which exists which is upwards of Rs. 200 and plus which we know of.

And then there is a private market. We believe in the private market, we have not decided yet on the pricing because again it is a question of volume. So, how much volume we can give to private market versus what we give to the government will define the pricing also.

So, I think there are a lot of moving parts, I believe it is not too far away, maybe in the next one to two weeks, we should be able to achieve that also post our approval. And as soon as we do that, we can give you an update on it.

Sameer Baisiwala: And just final, before I go is on Moraiya. Your guess is it going to be fiscal 22 when reinspection happens, or you think it can go beyond it keeping in mind the vaccination in the current COVID situation does not get any worse?

Sharvil Patel: I am still hopeful for fiscal 22 inspection and clearance. I mean because we just have to wait for an inspection now.

Moderator: Thank you. Our next question is from the line of Harit Ahmed from Spark Capital. Please go ahead.

Harit Ahmed: My first question is on Asacol HD. So, you had commented about slower offtake in the last quarter and the fourth quarter. So, have things normalized on this front, and anything that you are hearing on potential competition in this product, because there is a patent expiry that is quite imminent there?

Sharvil Patel: So, two things. Versus last year, we have seen obviously, the volumes for the brand, prescriptions come down. But if you see quarter-on-quarter, then they have stabilized. So, they are stable quarter-on-quarter. Over the last year their prescriptions have come down, as it has done for many products, post COVID. On respective competition, we currently believe, and we only know of one, we know one Company which has filed for the product.

And I do not think there are any products that have approved yet and post the patent expiry is only when we will probably get to know or a few weeks before that we will get to know but you know, we made an assumption that we will get to see one to two competitors in the market. That is our best estimate as of now.

Harit Ahmed: And on the Transdermal front, how many filings have we made till date, and how many of those are from Moraiya and then how many from the other facilities?

Sharvil Patel: So, we have I think two products from non-Moraiya facilities, and all the remaining rest are from Moraiya and one from our US facility. And Moriya is largely driving the contraceptive side of the Transdermal that we have filed for.

Harit Ahmed: And then last one on the COVID vaccine. On the two-dose vaccine will be immunogenicity and safety data that you have already generated will that suffice for approval, or will there be a requirement for full-fledged Phase-2 efficacy trial?

Sharvil Patel: So, it is the same amount of dose that we are giving. So, we strongly believe that this will suffice for the approval.

Moderator: Thank you. The next question is from line of Ranvir Singh from Sunidhi Securities Please go ahead.

Ranvir Singh: Sir, on ZyCoV-D side, just to understand are we working on any other delivery system for non-invasive like in nasal or something?

Sharvil Patel: Yes, so I said it was for our current vaccine it is already an intradermal application, and it is a needle free applicant of the dosing. So, it is already one of the I will say future ended technologies which are almost noninvasive, and which leads to very little side effects.

Ranvir Singh: And just for my understanding, visits and doses are different nomenclature or this is same?

Sharvil Patel: Sorry?

Ranvir Singh: Like we talk about two visits, and sometimes we talk about two doses. So, these two are different things or this is the same?

Sharvil Patel: So, before we used to give the vaccine over a period of three visits or three doses in the way. So, 0, 28 and 56. Now it will be over two visits 0 and 28.

Ranvir Singh: Okay so it is the same like having a two doses at two visits so this is the same? It is not like one visit may have more doses?

Sharvil Patel: No, the dose is still, earlier it was 2 milligrams over 3 times, now it is 3 milligrams over two times.

Ranvir Singh: And on Us genetic side the most of competition is middlemen products or we see across products that competition has impacted you know badly?

Sharvil Patel: No, it is across product.

Ranvir Singh: So, like Atorvastatin also we saw competition I think that said that would have also impacted Q1 results, right?

Sharvil Patel: As of the last four or five months the competition has been across portfolio for all of the generic companies. So, it is more wider it is not specific to a few products.

Ranvir Singh: Okay. And last one sir, related one. Like 35 products launches we are talking about and single digit growth. So, are you still so, competition or the price erosion is likely to be deeper going forward also or you see that now things are getting stabilized?

Sharvil Patel: So, we are seeing at least now a high single digit erosion, for obviously products, which are exclusive with there will be much more erosion, but generally you are seeing a high single digit erosion to the US business. And that is what we are predicting at least for the next couple of quarters.

Ranvir Singh: Okay. And you spoke about 30 to 35 product launches in India also in this year?

Sharvil Patel: Overall, yes.

Moderator: Thank you. The next question is from the line of Kedar from Nirmal Bang Institutional Equities. Please go ahead.

Kedar: Can you share your biosimilar revenues for the quarter and how much of that was from India? Also, if you could share some color on the biosimilar revenue that should shape up in the emerging markets over the next three years?

Sharvil Patel: So, on the biosimilars front, currently larger, most of our revenue is driven out of India only. In the next calendar year, we will see more launches in the emerging markets, and which will add to the overall revenue on the biosimilar side. On the biosimilar in India, we believe we will be I

am sure Vishal can give you the exact number, but I think we are about Rs. 350 crores right now, on an annualized basis and we get to see it to hit Rs. 500 crores soon.

So, that is where we are on the India biosimilars business. And globally, as I've maybe said earlier also that we have now nominated two biosimilar programs for global development, which will see commercialization post 2025. So, that is the current plan for biosimilars.

Kedar: Okay, and just to follow up on that, which are the key countries that you will be focusing on in the emerging markets? And do you have any plans to out license or market them on your own?

Sharvil Patel: So, current our biosimilar EM strategy, emerging market strategy is mostly licensing. If you look at which will be the focus markets, which will be also add good revenue to us, it will be the Latin American countries driven by Mexico and then Colombia, Venezuela, and others. In Asia, we are looking at Philippines, Thailand and Indonesia being the critical markets. And then obviously Sri Lanka and other smaller markets, Myanmar. In Middle East, we want to build towards the Saudi Arabia side of the market. And we also now have approvals in Russia.

So, Russia will become a critical market to sell for Russia and the CIS countries nearby. So, this will be the current plan for the EM markets. What is good for us is that we already have approvals in Russia. We have approvals coming now in Asia, and potentially soon approvals in Latin America also. So, this would help us build at least three to four biosimilars in all of these markets.

Kedar: Thank you for my question. Just a last question that in case you see a delay in Moraiya resolution to be potentially see a dip in US revenues?

Sharvil Patel: So, Moriya has important products, which are transdermal, which we need approvals for. So, they are important in terms of our future revenue. Most of the oral drugs are filed out of other parts, injectables also filed out of other sites. So, they will definitely have an impact. But over a period of time, it will not be meaningful.

Moderator: Thank you. The next question is from the line of Anubhav Aggarwal from Credit Suisse. Please go ahead.

Anubhav Aggarwal: Sharvil Bhai, one just out of curiosity. This 2mg in CMD doses. So, when this was so close, I am a little surprised that you started with such a large trial of 28,000 patients with 2mg dose, which because you very well knew that your vaccine is going to 3 dose vaccine. So, what was the hindrance of starting the trial with 3mg doses at that time?

Sharvil Patel: So, again, this is science that we have been doing, we are doing DNA vaccine for the first time. So, obviously, we would have not always known how everything moves and as we move forward, things we get to know because the immunogenicity and other data comes out much later and same does for animal data and other things. So, in this development cycle, things kept on happening parallelly and not in sequence. So, that is one part of the issue.

And the second is, we were also looking at it saying that if we have a longer time, in terms of gap, do we see a higher antibody response. And that could potentially also have been so that 3 dose made sense from doing that. What we are now getting to see is that two dose is also behaving similar or better. So, maybe that hypothesis was not fully there. And it is an intradermal delivery. So, we have to be always we had to make sure that we have an application possible that can be done in two doses, I mean, two times versus three visits.

And that also means because we have to only inject 100 microliters in a way. So, it is a noninvasive insertion, but we had to do it. So, we had to all of those were questions that still needed to be answered. So, that is what happened. And that is how the whole development journey went through. And now we believe that because the safety is similar, and obviously the immunogenecity is similar, it will end up being only two visits, but it will still be taken on both arms as it was done in the two milligram.

Anubhav Aggarwal: And the second question was on the US market, just trying to understand the erosion better in this quarter. So, was it that because of the COVID, the buyers were having a larger amount of inventory to stock with for the last year, and now they have started reverting back to the normal inventory? And that is why there was a pressure among suppliers because the volume went down from the buyers in terms of purchase. Was it like that the reason that the price erosion increased for everybody in this quarter?

Sharvil Patel: I think no, the buying came down and you can attribute some part to higher inventory. But that was mostly to do with last quarter, not this quarter, as the gone quarter by. But it is more now all-around higher competition. We are seeing far more new players with new approvals who seem to be very aggressive in pricing, which we believe in as for us, it is not practically possible and responsible to be going at such low pricing. So, that is what is happening to the current market.

So, we are seeing far more bids and far more challenges to pricing, which we believe will some of it seems irrational, but I think over a period of time or maybe some of this will stabilize. But that is the current scenario.

Anubhav Aggarwal: Just one more clarity on this US one. When you guide to low single-digit growth in the US business, so you expecting competition in the Asacol this year itself? And despite the competition, you are guiding for 2% to 3% growth?

Sharvil Patel: So, we are assuming at least one generic will be on the market. That is what our current assumption is on the immediate basis post patent expiry.

Moderator: Thank you. Ladies and gentlemen, due to time constraints, that would be our last question for today. I now hand the conference over to Mr. Ganesh Nayak for closing comments. Thank you and over to you, sir.

Ganesh Nayak: Thank you very much. And look forward to interacting with you again in the month of October when we declare our quarter two results for FY22. Thank you and have a nice evening.

Moderator: Thank you very much. Ladies and gentlemen, on behalf of Cadila Healthcare Limited that concludes this conference. Thank you all for joining us and you may now disconnect your lines.